SUMMARY OF CLAIMED SUBJECT MATTER

TREM-1 is a receptor of activation on macrophages. TREM-1 includes a soluble extracellular domain and a hydrophobic transmembrane domain (see Fig. 1) that when triggered by its ligand, the ligated complex induces macrophage activation. TREM-1sv is a variant of TREM-1 that is not anchored in the macrophage cell membrane but free to capture TREM-1 ligand. When TREM-1 ligand is captured by TREM-1sv the TREM-1 receptor complex is not triggered and the macrophages are not activated thus permitting the modulation (up or down activation) of macrophages, which in turn modulates the immune response.

The invention currently under examination is to a method of modulating an immune response including administering to an animal, in need thereof, a composition comprising a soluble polypeptide, a fragment, or an equivalent according to SEQ ID NO: 2, in an amount effective to modulate the levels of TREM-1 and /or ligand binding activity whereby the immune response is modulated in the animal.

Claims 1 and 3 are supported on pages 4-7, pages 11-14, page 19, figures 1 and 4 of the specification as originally filed. Claim 40 is supported at paragraph [0033] in the specification. Claim 41 is supported by Example 11. Claim 42 is supported at paragraph [0031].

STATUS OF AMENDMENTS

There are outstanding claim amendments in this RCE in response to the Decision on Request for Rehearing dated of November 5, 2008. We believe that no new subject matter is added as a result of these amendments.

AMENDMENTS TO THE CLAIMS

Claims 2, 4, 6-10, 12-14 and 17-39 are cancelled. Claims 1, 3, 5, 11, 15, 16 and 40-42 are active in this application. Claims 1, 3 and 11 are amended as follow. A version with tracked changes is presented in Appendix I.

1. (Amended) A method of modulating an immune response including administering to an animal, in need thereof, a composition comprising a soluble polypeptide, a fragment, or an equivalent according to SEQ ID NO: 2, in an amount effective to modulate the levels of TREM-1 and /or ligand binding activity whereby the immune response is modulated in the animal.

2. (Canceled)

3. (Amended) The method of claim 1, wherein said polypeptide, fragment or equivalent according to SEQ ID NO: 2 can have several additions, deletions, fusions and/or substitutions of amino acids in any combination.

4. (Canceled)

5. (Previously Presented) The method of claim 1 or 3, wherein said immune response is an inflammatory response.

Claims 6-10. (Canceled)

11. (Amended) The method of claim 1 or 3, wherein said polypeptide, fragment or equivalent are admixed with a pharmaceutical carrier.

Claims 12-14 (Cancelled)

15. (Previously Presented) The method of claim 1 or 3, wherein the animal is suffering from a disease or condition is selected from the group consisting of organ transplant/rejection, bone marrow transplant/rejection, graft versus host disease, infectious disease, and an autoimmune disease.

16. (Previously Presented) The method of claim 15, wherein the disease or condition is an infectious disease and which is septic arthritis or septic shock.

17-39. (Canceled)

40. (Previously Presented) The method of claim 15, wherein the disease or condition is an autoimmune disease and which is rheumatoid arthritis, lupus, multiple sclerosis and ulcer.

41. (Previously Presented) The method of claim 1, wherein the composition modulates LPS-induced cytokine production.

42. (Previously Presented) The method of claim 1 or 3, wherein the animal is a human.

STATUS AFTER DECISION ON APPEAL AND DECISION ON REHEARING

After the Hearing of March 6, 2008 and the Decision On Request For Rehearing of November 5, 2008, the rejection of claims 1, 3, 5, 11, 15, 16 and 40-42 under 35 U.S.C. § 112 first paragraph, as drawn to new matter, is reversed. The rejection of claims 1, 3, 5, 11, 15, 16 and 40-42 under 35 U.S.C. § 102(e), as anticipated by Wang is reversed. The rejection of claims 1, 3, 5, 11, 15, 16 and 40-42 under 35 U.S.C. § 112 first paragraph, as lacking enablement, is affirmed. The rejection of claims 1, 3, 5, 11, 15, 16 and 40-42 under 35 U.S.C. § 102(e) as anticipated by Reuben is affirmed. The Board has acknowledged that SEQ ID NO: 478 is different from SEQ ID NO: 2 (DRR p. 4).

REMARKS /ARGUMENTS

A. The first objection remaining is whether Claims 1, 3, 5, 11, 15, 16 and 40-42 are sufficiently described in the specification so as to be enabled under the meaning of 35 U.S.C. § 112, first paragraph.